Standard Operating Procedure
for

Laboratory Assessment and Assessment Report

Revision 8

Laboratory Services Division

Office of Environmental Assessment

Louisiana Department of Environmental Quality

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STANDARD OPERATING PROCEDURES FOR ON-SITE LABORATORY ASSESSMENT AND ASSESSMENT REPORT

SOP #LELAP T-004

1.0 Purpose

1.1 This standard operating procedure (SOP) establishes the requirements for procedures used by the Louisiana Environmental Laboratory Accreditation Program (LELAP, the Program) to conduct an on-site assessment (assessment). The on-site assessment is used to determine initial and continuing compliance with the Louisiana Administrative Code, Part I, Subpart 3, Laboratory Accreditation regulations, the National Environmental Laboratory Accreditation Conference (NELAC) Standards, and when appropriate The NELAC Institute Standard (TNI). This SOP also applies to mobile laboratories as defined by NELAC, 4.0(d).

2.0 Frequency of Assessment

2.1 The Louisiana Department of Environmental Quality (LDEQ), LELAP regulations, and NELAC Standard require a comprehensive on-site assessment of each accredited facility every two years. It shall be the responsibility of the LELAP Assessor (Assessor) to conduct an assessment at a minimum of once every two years. Assessments conducted by the Assessors may be conducted more frequently at the discretion of the Laboratory Services Division (LSD) Administrator (the Administrator) or LELAP Supervisor.

2.2 Emission Testing facilities shall receive a home-base assessment and field assessment every two years. Whenever feasible the home-base assessment and field assessment shall be scheduled at the same time and where practical shall coincide within the same week. Assessments conducted by the Assessors may be conducted more frequently at the discretion of the Laboratory Services Division (LSD) Administrator (the Administrator) or LELAP Supervisor.

3.0 Announced and Unannounced Assessments

3.1 The Assessor shall schedule the initial on-site assessment with the applicant laboratory. Initially, the Assessor shall contact the laboratory representative via the telephone. The date of the assessment shall be scheduled at that time and a letter will be sent that confirms the date and time of the assessment. That written notification will include a "CD" that contains at a minimum Checklist CL-10, NELAC method checklists, a copy of the Louisiana Administrative Code Laboratory Accreditation Regulations, and Chapter 5 2003 NELAC Standard and confidential business information.

3.2 Assessors have the authority to conduct either announced or unannounced on-site assessments whenever necessary to determine the extent of the laboratory's compliance with the

LELAP regulations or NELAC Standards. The Administrator or LELAP Supervisor must approve any unannounced on-site assessment.

3.3 Assessors will work with Federal departments/agencies/contractors to expedite the attainment of all necessary clearances, and such clearances shall be obtained as far in advance as possible.

4.0 Follow-up Assessments

4.1 LELAP representatives may conduct follow-up assessments at laboratories where findings have been identified by previous assessments.

4.2 Assessors may use follow-up assessments to determine if the laboratory has corrected findings, or at the request of the laboratory to determine compliance with regulations and standards.

4.3 When, in the judgment of the Accreditation body, findings are of such severity as to possibly warrant the downgrading of a laboratory's accreditation status, the assigned Assessor shall conduct a follow-up assessment within thirty (30) calendar days after the approved corrective action plan has been implemented. The Assessor shall have thirty (30) calendar days to complete the assessment report. At that time any findings left uncorrected from the previous assessment shall be viewed as grounds for disaccreditation or suspension. The process for disaccreditation or suspension shall begin immediately.

5.0 Changes in the Laboratory

5.1 When a change occurs in a laboratory's ownership, location, key personnel, or major instrumentation, notification of the accreditation body is required within 30 days (Section 4.3.2). LELAP shall evaluate the significance of a change that might alter or impair the laboratory's capability and quality, and indicate to the laboratory the results of their evaluation in writing. LELAP shall retain records to indicate that such an evaluation was conducted. LELAP will conduct an assessment of any laboratory that changes locations within thirty (30) calendar days of completion of the laboratory's move.

6.0 On-Site Assessment Schedule and Format

6.1 An on-site assessment will be conducted by LELAP Assessors, in accordance with standards recognized by NELAP and as required by state regulation. The on-site assessment is an integral requirement of the laboratory accreditation program and one of the primary means by which a laboratory's capabilities and qualifications are evaluated.

6.2 The assigned Assessor will schedule the initial on-site assessment with the applicant laboratory. The Assessor shall not schedule the assessment with the laboratory until it has been determined that the laboratory has submitted a complete application. *LELAP shall not proceed*

with any assessment until all applicable fees have been paid to the State. Subsequent on-site assessments do not have to be scheduled in advance by Assessors.

6.3 The Department reserves the right to conduct scheduled and unscheduled on-site assessment to determine compliance with these regulations. In the event of scheduled assessments, the laboratory will be notified in advance for assessments related to the biennial on-site review requirement of the Louisiana Administrative Code, Part I, Subpart 3, §4709.C. The written notification will establish the intent of LELAP to conduct the required on-site assessment that supports the laboratory application for initial or continuing accreditation. The letter will provide the following:

6.3.1 proposed schedule;

6.3.2 notification that all information must be updated as required by the Louisiana Administrative Code, Part I, Subpart 3, §5707;

6.3.3 identification of assessors including any third party assessors under contract to LELAP and notification of expenses related to third party assessment;

6.3.4 electronic copy of current applicable regulations;

6.3.5 electronic copy of all checklists to be completed by the laboratory prior to the on-site assessment along with detailed instructions on how to complete the checklists;

6.3.6 notification that all submissions must be received as electronic copies and hard copies by LELAP no later than two weeks prior to the on-site assessment; and

6.3.7 notification that any claim of Confidential Business Information (CBI) must be made within thirty days of the confirmed date of receipt of the letter.

6.4 The written notification will include a list of documents required by the assessors prior to the on-site assessment. The documents required at a minimum but not limited to:

6.4.1 Complete list of all quality system documents including the Quality Assurance Manual (QAM) and all SOPs currently in force at the laboratory. The list must include the title, unique identification number, date of issue, date of last revision, and date of last review.

6.4.2 Copies of all test method SOPs for which accreditation is being sought including any related SOPs such as sample receipt and log in, sample preparation, calibration, quality assurance/quality control (QA/QC), and data review and reporting. Documents must be provided in both hard copy and electronic copy.

6.4.3 Up-to-date organizational chart and employee roster including job assignment(s);

6.4.4 An up-to-date list of all staff training related to the performance of analyses, e.g. initial demonstration of capability by method, vendor training courses, any other relevant training.

6.5 During the on-site assessment, the Assessor or Assessment Team will collect and evaluate information and make observations to determine if the laboratory is in conformance with regulations and applicable standards. An assessment team may include technical support personnel approved by LELAP. These individuals need not be formally qualified by LELAP as assessors, but these individuals still must meet the requirements of the standards concerning conflicts of interest and professional conduct. Members of the assessment team who provide technical assistance but are not qualified as assessors are not eligible to conduct interviews in the absence of the assessor or to cite any findings.

6.6 The Administrator and the LELAP Supervisor shall insure through training and seminars that all Assessors conduct uniform and consistent assessments, in order to:

6.6.1 allow confidence in comparison of results generated by different laboratories;

6.6.2 facilitate recognition by other accrediting agencies; and

6.6.3 promote acceptance of the accreditation standards by the regulated community.

6.7 If a third party assessor is used, LELAP shall provide the third party assessor copies of all essential correspondence related to the scheduled laboratory assessment. Third party assessors shall be notified by the LELAP Supervisor or his designee of their laboratory assessment assignments. It is the responsibility of the third party assessor to schedule, perform and draft assessment reports within the contract time frames.

6.8 Combined home base and field assessments

6.8.1 Per LAC 33:I.4709.E, stack testers and facilities with mobile laboratories are required to have two assessments: one of the home base and one of the mobile or field units in the field. To facilitate the keeping of required assessments on schedule as required by LAC 33:I.4709.C and LAC 33:I.4709.F, and to reduce the potential for confusion of findings determined during the two assessments and corrective action taken for said findings, assessors shall proceed as described below.

6.8.2 The home base assessment and the field assessment shall be scheduled within five weeks of each other. The assessment findings shall be combined into one report.

6.8.3 The preference is that the field assessment shall be conducted at an active site, in coordination with the site owner or management.

6.8.4 If an active site is not available within five weeks of the home base assessment, the assessor shall schedule the stack tester or mobile laboratory for a static assessment, to be conducted at the home base or at the LDEQ Laboratory Services Division laboratory, as follows:

6.8.4.1 Static Field Assessments at the LSD Building

6.8.4.1.1 Logistics

6.8.4.1.1.1 The assigned Assessor must contact the stack tester and schedule a field test. If the stack tester is not able to provide a date for a field assessment, then the Assessor must schedule a static field test at the laboratory and notify the stack tester of the materials necessary to perform the static field test. At this time the Assessor must request the electrical requirements for the mobile facility.

6.8.4.1.1.2 Once the date for the assessment is scheduled, the Assessor must notify Safety Officer or his designee, Administrative Analyst, and the Laboratory Services Division Administrator as to when the static field test has been scheduled. A notification will be sent to Office of State Building (OSB) requesting that a state electrician be available the morning of the static field assessment. The electrician must be provided with the electrical requirements of the mobile facility at this time.

6.8.4.1.1.3 The day before the static field assessment a second notice must be sent to OSB reminding them of the need to have an electrician on site during the start of the static field assessment.

6.8.4.1.1.4 The morning of the static field test, the assigned Assessor must be available at the laboratory prior to the scheduled static field test in the event that the stack tester arrives early. Once the stack tester and electrician are on site, the Division Administrator and the Safety Officer are to be notified. The stack tester is to be directed to the back of the LSD building and should park on the right hand side of the drive just prior to the covered portion of the drive. The electrician should be escorted to the electrical room so that he can wire the trailer or adapter to the LSD building. The electrician will be notified at this time as to when the static field test will be completed. This should not exceed 7 hours.

6.8.4.1.1.5 The Assessor and stack tester personnel will insure that the OSB electrician has disconnected the mobile facility before the closing briefing. If the OSB electrician has not arrived as the required time, the Assessor will notify the administrative analysts, Safety Officer or the Administrator so that OSB can be notified that the static field test is over.

6.8.4.1.2 Technical

6.8.4.1.2.1 The assigned Assessor will meet with the stack tester personnel to conduct the opening briefing. The methods to be assessed will be discussed at this time, as well as any comments the Assessor has on documents reviewed prior to the mobile facility arriving at the laboratory.

6.8.4.1.2.2 Once the opening briefing has occurred, the stack tester personnel and the Assessor will return to the mobile facility so that the stack tester personnel can assemble the sampling train. The Assessor will interview the stack tester personnel to discern their knowledge with regards to specifications for sampling trains.

6.8.4.1.2.3 The Assessor will verify calculations used for reference method 1 (Traverse Points).

6.8.4.1.2.4 The Assessor will review calibration records for each of the analyzers required for the static field assessment. At this time the Assessor will verify that the mobile facility has calibration records, equipment and maintenance logs for each analyzer contained in the mobile facility. Training records for each analyst assigned to the mobile facility will be reviewed to insure that persons assigned to the facility have been trained to operate all analyzers available during the static field test. The Assessor will verify that the analyst assigned to the mobile unit have read and understand the Standard Operating Procedures used during the static field test.

6.8.4.1.2.5 The Assessor and stack tester personnel will conduct the exit briefing to discuss any findings identified during the static field test. A written report of the preliminary findings will be given to the stack tester personnel at that time.

6.8.4.2 Static field assessments at the stack tester home base

6.8.4.2.1 Logistics

6.8.4.2.1.1 This assessment should take place at the home base location at the same time as the bi-annual home base assessment. The following outline provides a stepwise approach to the assessment.

6.8.4.2.1.2 The Assessor shall select the methods listed in the stack tester scope that are based on the use of in-line monitors or continuous emission monitors during the pre-assessment phase.

6.8.4.2.1.3 The Assessor shall establish an acceptable schedule with the stack tester such that a field trailer that is actually used at client locations is available at the home base along with the test equipment modules related to the tests being assessed.

6.8.4.2.1.4 After the field procedure assessment, the home base assessment will occur as currently done.

6.8.4.2.2 Technical

6.8.4.2.2.1 Upon arrival at the assessment location, the Assessor shall notify the stack tester which tests will be assessed. In most cases this can include all the fixed gases, oxides of carbon, nitrogen and sulfur, sulfur-containing gases, low molecular weight hydrocarbons, etc. The stack tester staff will then set up the monitoring equipment under the eyes of the Assessor and conduct initial calibrations as required by the method using calibrants from the stack tester stocks.

6.8.4.2.2.2 The analysis of target analytes will be from cylinders of proficiency test gases purchased and arranged for by the stack tester for the scheduled assessment. This will help address the issue of failure to run the required PTs which is frequently found in stack tester operations.

6.8.4.2.2.3 The off-line analysis of parameters such as ammonia from entrapment trains (CTM-027) can occur on-site or be shipped to an off-site laboratory based on the stack tester normal manner of operation.

6.8.5 The Assessment Report (AR) will be prepared and submitted to the stack tester in the normal time frame. The stack tester corrective action plan submitted in response to the AR will report the PT results associated with the LELAP-observed test procedures.

6.8.6 LELAP will establish acceptable levels of performance for stack tester accreditation based on the completed corrective actions.

6.8.7 Neither static field assessment approach will assess the field implementation of tests which monitor physical properties such as velocity, opacity, moisture content, and particulate load/characteristics. These assessments will rely upon review of data packages.

7.0 Off-Site Review of Laboratory Documentation

7.1 Assessors shall review the laboratory's records from the LELAP files prior to the assessment to insure that the records are complete, and that it contains all of the original documents. In addition, the Assessor shall review any documents submitted by the laboratory in preparation of the on-site assessment.

7.1.1 Documents reviewed may include but are not limited to:

7.1.2 Copies of previous assessment reports and proficiency test results;

7.1.3 General laboratory information such as laboratory submitted self-assessment forms, e.g. checklists, SOPs and Quality Assurance Plan(s);

7.1.4 Official laboratory communications and associated records with appropriate accreditation body staff;

7.1.5 Available documents from recipients of reports from the laboratory;

7.1.6 The laboratory's application for accreditation;

7.1.7 Copies of current approved analytical test methods for which the laboratory has requested accreditation; and

7.1.8 LELAP and/or State records pertaining to the applicant laboratory.

7.2 At a minimum, sufficient test method SOPs shall be reviewed to cover a representative example of the analytical work covered by the scope of accreditation. Each Assessor shall establish and document the exact list of SOPs for review after consultation with the laboratory's designated representative.

7.3 The assigned Assessor shall review the QAM, test method SOPs, completed checklists and other documents as necessary and note any items that should require clarification during the on-site assessment. These notes will be written in the form of a preliminary list of findings for the assessment.

7.4 Assessor shall determine the details of the assessment. The application will always determine the scope of the initial assessment. The scope of subsequent assessments will be determined by LELAP staff and the LELAP Supervisor.

8.0 Assessor Documentation of On-Site Assessments

8.1 During the on-site assessment, Assessors will collect information and make observations to be used to evaluate the laboratory's compliance with established state accreditation regulations and NELAC standards. Any area of non-compliance shall be written as a finding.

8.2 The Assessor shall review laboratory records to determine whether the testing laboratory has maintained the necessary documentation to technically substantiate previously issued reports.

8.3 Assessors shall document all observations to be included in the exit report and the final formal assessment report in an objective manner. Any observations that may result in a finding shall be added to the preliminary list of issues identified during the off-site assessment (see section 7.4).

8.4 During the assessment, sufficient information may become available to suspect that a particular person has violated an environmental law or regulation, such as knowingly making a false statement on a report. This information must be carefully documented since further action may be necessary. In the event that evidence of improper and/or potentially illegal activities have or may have occurred, the assessment team must present such information to the accrediting body for appropriate action(s). The LELAP Supervisor and/or the LSD Administrator must be notified immediately by the lead assessor. These issues, at the discretion of the accreditation body, may or may not be subjects or issues of the closing conference. However, the assessor must continue to gather the information necessary to complete the accreditation assessment.

8.5 The Assessor's notes, exit report and formal assessment report must include the date and time of the assessment, all personnel present during the opening and closing briefing/debriefing, staff interviewed and date and time of the closing briefing. The Assessor is required to sign and obtain the signature(s) of the laboratory representative(s) on the official copy of the exit report.

8.6 Inappropriate personal observations shall not be included in the official assessment records or in any preliminary findings or notes.

9.0 Length of Assessment

9.1 Assessors shall consider the following factors when conducting an assessment: the number of tests for which a laboratory desires accreditation; the number of Assessors available; the size of the laboratory; the number of possible findings encountered during the assessment; and the degree of laboratory staff cooperation.

9.2 The Assessor shall stop an assessment if the laboratory staff is not fully supportive. The Assessor shall notify the LELAP Supervisor and the LSD Administrator as soon as the assessment is discontinued. The Assessor shall act in the manner described to him by the Administrator of the Program at this time.

9.3 The LELAP Supervisor shall insure that an adequate number of Assessors are assigned to complete an assessment within a reasonable period of time. A reasonable period of time shall be considered 1-2 days for small laboratories and 2-4 days for large laboratories. The actual length of the assessment will be determined by the on-site assessment. If an assessment must be lengthened due to any circumstances the LELAP Supervisor and/or LSD Administrator must be notified by telephone as soon as the Assessor is aware of the need to extend the assessment.

10.0 Opening Conference

10.1 Assessors shall arrive at the laboratory during the laboratory's established working hours.

10.2 The responsible laboratory official(s) will be contacted soon as the Assessor or Assessment Team arrives on the premises of the laboratory.

10.3 The assigned Assessor shall conduct an opening conference that will address the following topics:

10.3.1 identification of the assessment team and discussion of the agenda;

10.3.2 the purpose of the assessment;

10.3.3 the standards and/or regulations that will be used by the Assessor in judging the adequacy of the laboratory operation;

10.3.4 discussion of any questions the laboratory may have about the assessment process;

10.3.5 the procedures related to Confidential Business Information;

10.3.6 analyses that will be examined;

10.3.7 records and operating procedures to be reviewed during the assessment and the names of the individuals in the laboratory responsible for providing the Assessor with the necessary records;

10.3.8 roles and responsibilities of key managers and staff in the laboratory;

10.3.9 safety procedures that the laboratory may require for the protection of the Assessor while in certain parts of the facility (under no circumstance shall an Assessor be required or even allowed to sign any waiver of responsibility on the

part of the laboratory for injuries incurred by the Assessor during an inspection to gain access to the facility);

10.3.10 presentation of the assessment appraisal form to the responsible laboratory official (for submission to the accreditation body); and

10.3.11 the tentative time and date of the exit conference.

10.4 The Assessor shall provide a copy of the preliminary findings from the off-site assessment of laboratory documents (see section 7.4) to the laboratory representative(s) during the initial briefing unless it is mutually agreed upon that such findings will be presented as of the closing conference and included in the exit report.

11.0 Laboratory Staff Interviews

11.1 The Assessor shall have the authority to conduct interviews with any and all of the laboratory staff. Interviews with regards to analyses must be conducted with the laboratory personnel responsible for the analytical procedure. If the QA officer or any member of the Laboratory's administrative staff tries to answer for an analyst, the Assessor shall ask that person to please give the analyst a chance to answer the question. Then if the analyst can't answer the question, the Assessor must rephrase the question and ask the analyst again. If the analyst still can not answer the question, then the Assessor shall direct the question to the QA officer or Laboratory Supervisor that is present.

11.2 The Assessor shall assess calculations, data transfers, calibration procedures, quality control/assurance practices, adherence to SOPs and report preparation for each ***selected*** test with the appropriate analysts.

11.3 Assessors are not required to discuss any **potential** findings during the interview process. Assessor shall discuss **potential** findings at the end of each day of the assessment if the laboratory requests and during the closing conference. **Potential findings identified during the off-site review, staff interviews, and on-site observations that are not satisfactorily addressed prior to the end of the closing conference shall be included in the formal exit report.**

12.0 Records Review

12.1 Assessors shall review records for accuracy, completeness and the use of proper methodology for each test and analyte to be evaluated.

12.2 The following minimum record set shall be reviewed by the Assessor(s):

12.2.1 application for accreditation;

12.2.2 previous assessment results and reports including proficiency testing results;

12.2.3 laboratory management structure and chains of responsibility (e.g. organizational charts);

12.2.4 qualifications of all key staff involved in the analysis or reporting of results for which accreditation has been requested;

12.2.5 quality assurance plan(s) for the laboratory;

12.2.6 sample receipt, handling, storage practices, and documentation

12.2.7 standard operating procedures (SOPs) and/or methods for selected parameters**,** including any associated sample preparation procedures and analytical reagent stoichiometry (ratio of sample, solvents, reagents*)*;

12.2.8 maintenance and calibration records of laboratory equipment and instrumentation;

12.2.9 preparation and standardization of stock solutions and standard reagents;

12.2.10 origins, purities, assays and expiration dates of primary standards, analytical reagents and standard reference materials;

12.2.11 records associated with method-specific QA/QC requirements;

12.2.12 specific records associated with the initial method validation study in the laboratory, including the historical calibration data;

12.2.13 report formats including the case narratives;

12.2.14 receipt and handling procedures for proficiency test (PT) samples;

12.2.15 internal audit reports and corrective action taken by the laboratory; and

12.2.16 documentation of the annual and/or ongoing management review of the laboratory.

12.3 If the laboratory requests that information obtained during the assessment be confidential, then the Assessor shall treat the information as confidential until such a ruling can be made by the Department Secretary. The Assessor shall notify the laboratory that a request for confidentiality can only be granted by the Department Secretary and that the request must be made in writing.

13.0 Closing Conference

13.1 The LDEQ LELAP Assessment Team will confer prior to the exit briefing to discuss and consolidate their findings.

13. 2 The LDEQ LELAP Assessment Team will schedule a time for the exit briefing. Indicate that sufficient time will be allotted to answer any questions the laboratory may have, within limitations imposed by travel arrangements or normal laboratory hours.

13.3 The exit briefing shall, at a minimum, include a draft of the exit report in electronic form, to be printed and provided to the appropriate laboratory personnel. This should be provided with sufficient time allotted for the appropriate personnel to read the report and formulate questions. The format of the report shall consist of a table with three columns for the finding number, description of the finding, and citation of the applicable regulation or standard.

13.3.1 Initial discussion shall include the following:

13.3.1.1 Thank the laboratory personnel for their hospitality and assistance in the audit.

13.3.1.2 Summarize positive attributes of the organization.

13.3.1.3 Explain that these are preliminary findings and observations and that more may be added or some deleted as the reporting process is finalized. Note that LDEQ is the final decision maker with regard to whether a specific condition represents a finding, and that if the laboratory disagrees with a finding, they are free to explain why they disagree in their corrective action response. While not required, ask if the laboratory disagrees with any findings. Indicate that if they disagree, the laboratory may explain their viewpoint to LDEQ in the corrective action response. Also emphasize that the exit report is not the same as the final assessment report.

13.3.2 Following discussion shall include the following:

13.3.2.1 Ask if the laboratory personnel have any questions regarding the findings.

13.3.2.2 Respond as necessary, answer any questions and clarify the findings and observations.

13.3.2.3 State that if there are no further questions, or if there are no aspects of the findings that, in the judgment of the lead assessor, require further clarification, explain as appropriate.

13.3.2.4 Explain the corrective action process:

13.3.2.4.1 The laboratory must submit a corrective action plan (CAP) that addresses each of the cited findings, using the electronic copy of the Finding Report included with this Assessment Report. These are separate files.

13.3.2.4.2 The laboratory response must be concrete, detailed, and specific, and must describe how the corrective action will be implemented and incorporated into the laboratory's quality system documentation.

13.3.2.4.3 The laboratory must include a proposed date of completion for each finding and the name of the person responsible for completing the corrective action. Enter the laboratory corrective action response to each finding in the appropriate spaces provided on the attachment. An example is provided in the findings section of the report, in which the sections to be completed by the laboratory are indicated by italics.

13.3.2.4.4 A paper copy and an electronic copy of the completed CAP must be submitted to LELAP within 30 days of the date of receipt of this report. All corrective actions must be completed satisfactorily within six months of the date of receipt. Note that LDEQ will verify that corrective actions are implemented in subsequent audits.

13.4 All present should sign and date the assessor's copy of the exit report. A separate form may be used if the number of signatures is too large to fit on the exit report. Note that signing the report does not imply that the laboratory personnel agree with the findings, but only that it was reviewed and understood in the exit briefing.

13.5 Make sure the scope (with any edits) and the checklist(s) are signed by the laboratory. Verify that if available, electronic copies of the laboratory's procedures are provided to the auditor(s).

13.6 If CBI was declared, make sure all information is so marked and that CBI forms are signed by the laboratory.

13.7 Provide the laboratory representative(s) with inspector evaluation forms for each inspector (see Appendix B of this SOP).

13.8 The exit debriefing is not required following a field assessment if the field assessment is combined with the home base assessment; in all other cases, the policy shall be followed for field assessments. All field assessments shall be documented with a signed attendance sheet and initialed scope following the completion of the assessment. Assessors conducting home base assessments shall follow this policy.

14.0 Reporting Procedures

14.1 The assigned Assessor shall complete a formal assessment report within 30 working days of the assessment. If the laboratory is accredited by the state of Louisiana only, the assigned Assessor shall have 60 working days from the last day of the assessment to complete a formal assessment report. The report shall be signed and dated by the Assessment team and LELAP Supervisor and sent to the laboratory through certified mail.

14.2 The laboratory must submit a corrective action plan to LELAP within thirty (30) calendar days from the date of receipt of the report. Once the plan has been received by LELAP it will be

date stamped by the Program Analyst and entered into the AAMS Database; a route slip shall be attached identifying the document prior to be sent to the appropriate LELAP Assessor.

14.3 Exceptions to adherence to these deadlines may be allowed at the discretion of the LSD Administrator or LELAP Supervisor. The laboratory must request the extension in writing and must explain the necessity for the extension. **The extension shall not automatically be granted**. The assigned Assessor must respond to the request within 10 working days of receiving the written request for an extension.

14.4 Assessment reports will be generated in a narrative format. Documentation of existing conditions at the laboratory shall be included in each report. All assessment reports will include a "List of Findings." The "List of Findings" shall be in conventional outline format and numbering.

14.5 Assessor reports shall contain the following**:**

14.5.1 Identification of the laboratory (name and address) in a formal transmittal letter**;**

14.5.2 Date (or dates) and time (beginning and end) of the assessment;

14.5.3 Identification and affiliation of each assessment team member;

14.5.4 Identification of participants in the assessment process;

14.5.5 A statement of the objectives of the assessment [assessment scope], including correction of prior findings, if applicable;

14.5.6 Assessment findings (deficiencies), requirements in tabular form that includes a summary of the objective evidence supporting the findings and the citation to the requirement that is not met; and

14.5.7 A list of attachments which may include but is not limited to:

14.5.7.1 Attachment 1 – Laboratory organizational chart;

14.5.7.2 Attachment 2 – Staff roster (with initials of interviewees);

14.5.7.3 Attachment 3 – List of laboratory SOPs (initial those reviewed);

14.5.7.4 Attachment 4 -- List of data packages reviewed on-site (by unique laboratory number);

14.5.7.5 Attachment 5--List of PT studies reviewed;

14.5.7.6 Attachment 6--All checklists completed by the laboratory;

14.5.7.7 Attachment 7--Signed copy of the exit report;

14.5.7.8 Attachment 8--Copy of any invoices submitted to the laboratory by a third party assessor (if necessary); and where applicable.

14.5.7.9 Attachment 9—the application

14.5.8 The report shall be formatted as illustrated in Appendix A of this SOP.

14.6 The assigned Assessor shall insure that the findings within the final report are consistent with established regulations and standards.

14.7 Assessment reports generated by LELAP third party Assessors shall follow the same protocol as for LELAP Assessors. Once the third party Assessor has crafted the assessment report and placed a "Draft" watermark on the report and the date of the draft, it will be sent electronically via e-mail to the LELAP Supervisor. The LELAP Supervisor shall have one (1) working day to forward the draft Assessment report to the appropriate LELAP Assessor for review.

14.8 The LELAP Assessor shall have two (2) working days from receipt of the "Draft" report to review and comment on any changes that need to be made to the report. The "Draft" document with or without comments is then sent from the LELAP Assessor to the LELAP Supervisor for review via e-mail.

14.9 The LELAP Supervisor shall then review the Assessment Report and any comment from LELAP and if he/she concurs shall forward the information on to the third party Assessor. If the Supervisor does not agree with the review comments then the "Draft" report shall be sent back to the appropriate LELAP Assessor to make additional changes. The LELAP Assessor will now have one (1) working day to complete the requested changes and return to the LELAP Supervisor.

14.10 The LELAP Supervisor shall have one (1) working day to insure that all requested changes have been made and then forward to the appropriate third party Assessor. If the third party Assessor is required to make changes to the document they shall have two (2) working days to make the changes and resubmit to the LELAP Supervisor via e-mail. The revised draft shall be watermarked "Draft" and the new revision date added.

14.11 Once LELAP has approved all requested changes in the "Draft" Assessment report, the third party Assessor will mail the complete Assessment Report package to LELAP. The LELAP Supervisor will have two (2) working days to review the completed report and sign. The signed report will be shipped via certified mail to the Laboratory and copy of the signed report will be placed in to the laboratory's records in the LELAP file room.

14.12 During this last review of the Assessment report if there are any minor editorial changes such as a period in the wrong place or misspelled word, it will be corrected with a single line drawn through it, initial and dated and the correction made by hand. The cover letter to the laboratory will indicate that there are "minor differences" between the electronic copy of the report and the printed copy. The differences will be identified in the cover letter. A copy of this cover letter and the corrected page(s) will be sent to the third party Assessor for their records.

15.0 Report Distribution

15.1 The laboratory shall receive a copy of the signed assessment report from LELAP. The report shall be sent by certified or registered mail and on occasion as deemed appropriate by the LELAP Supervisor via FedEx.

16.0 Release of Report

16.1 On-site assessment reports will be released by LELAP.

16.2 The reports shall be released to the responsible laboratory official(s) within thirty (30) working days after the last day of the on-site visit.

16.3 The assessment report shall NOT be released to the National Accreditation Database until findings of the assessment and corrective actions have been completed. All Confidential Business Information (CBI) and information related to national security shall be stricken from the report in accordance with prescribed procedures, and the report provided to the laboratory.

16.4 The assessment report shall become public record once the report has been provided to the laboratory as required by statute.

16.5 In accordance with the Freedom of Information requirements, any documentation adjudged to be proprietary, having financial and/or trade information, or relevant to an on-going enforcement investigation shall be considered to be exempt from release to the public.

17.0 Record Retention Period

17.1 LELAP shall retain copies of all assessment reports, checklists, and laboratory responses for a period of at least ten (10) years or longer if required by specific State or Federal regulations.

17.2 Third parties involved in the assessment shall retain all records for the period of time stipulated in the contract with LDEQ. No records shall be disposed of by the third party contractor without the written permission of the LDEQ contract official.

18.0 QA/QC Documentation for the Laboratory Audits

18.1 The primary quality assurance for the documentation is the review of the record by the LELAP Supervisor and his/her designee.

18.2 At the close of the On-site assessment, the laboratory representatives must sign-off on the findings document as well as any of the laboratory representatives present at the time of de-briefing.

Appendix A
Assessment Report Format

Assessment Report

for

[LAB NAME]
[ADDRESS]
[CITY, STATE ZIP]

Designated Representative: <*Name of Lab Representative*>

Performed:
[DATE]

SUBMITTED TO:
Melvin C. Mitchell, Sr.

Louisiana Department of Environmental Quality
Office of Environmental Assessment
Laboratory Services Division
P. O. Box 4314
Baton Rouge, LA 70821-4314

Submitted by: [Assessor name]
_____

Reviewed by:
_____

[Contractor Name or LELAP]
[Contractor Address]

Issue Date: _____

8.6.A.1.1.1.1.1.1 ASSESSMENT REPORT

Scope

<*Laboratory Name*> has been granted accreditation by the Louisiana Environmental Laboratory Accreditation Program (LELAP, the Program) for <*general description of scope*>.

The Assessor must include introductory information regarding the assessment such as date and time, Scope of the accreditation and any other information that the Assessor deems appropriate. Please include information on size of laboratory and number of employees. The report must identify the lead assessor and any other assessor present during the assessment.

This report and the attached tables represent the conditions observed in the facility at the time of the assessment. Table 1 represents the Standard Operating Procedures that were reviewed as part of this assessment. Conditions identified in the course of the assessment that fail to satisfy the requirements of LAC 33, Part I, Subpart 3 are described in the attached List of Findings. An electronic copy of the List of Findings, in MS Word format, is included on the enclosed CD, to be used by the Laboratory to prepare their corrective action response.

Summary Review

Table 2 describes the quality system components (organization and management, training, test methods, reports, etc.) that were reviewed during the assessment.

Data Package Review

A list of the data packages that were reviewed during the assessment is shown in Table 3. Electronic copies of the data packages and other materials reviewed are included as attachments on the enclosed CD.

Observations

This section is to be used for information that, in accordance with the judgment of the assessor, is necessary to provide a more accurate picture of the laboratory and/or its operations.

Table 1 Materials Selected for Review		
Parameter	**Reference Method**	**Standard Operating Procedure**

Table 2 **Summary Review**	
Quality Component	**Findings Identified**
Organization	<# 2, #7-10>
Quality System	#1, #5
Document Control	None identified
Subcontracting	etc
Purchasing	
Complaints	
Corrective Action	
Records	
Internal Audits/Management Reviews	
Personnel	
Environment	
Equipment	
Test Methods	
Traceability & Calibration	
Sample Handling	
Proficiency Tests	
Reporting	
Additional areas as appropriate	

Table 3 Review of Data Packages and Other Materials	
Parameter	**Data Package Identifier (Sample #'s)**

Attachments

The enclosed CD contains electronic copies of the attachments listed below.

Attachment 1. Assessment Findings Form (Exit Report) and Signature Sheet.

Attachment 2. Pre-Assessment Checklist.

Attachment 3. …..

etc

<The list of Attachments should include the following: exit report; pre-assessment checklist; application and/or scope of accreditation; attendance at initial and final briefings; SOPs reviewed during the assessment; completed quality system checklists; and other documents as appropriate.

For attachments that are not scanned onto the CD, paper copies must be attached after the List of Findings. Paper copies are NOT required for attachments that have been scanned onto the CD enclosed with the assessment report.>

LIST OF FINDINGS

Attached is a list of the findings that were identified during the on-site assessment and the review of the laboratory's documents and records. Each numbered item identifies a specific finding and references the LAC/NELAC citations that establish the requirement that was not met.

The laboratory must submit a corrective action plan (CAP) that addresses each of the cited findings, using the electronic copy of the List of Findings included with this Assessment Report. The laboratory response must be concrete, detailed, and specific, and must describe how the corrective action will be implemented and incorporated into the laboratory's quality system documentation. Your response must include a proposed date of completion for each finding and the name of the person responsible for completing the corrective action. Enter your corrective action response to each finding in the appropriate spaces provided on the attachment. An example is provided below, in which the sections to be completed by the laboratory are indicated by italics.

A paper copy and an electronic copy (in MS Word format) of the completed CAP must be submitted to LELAP within 30 days of the date of receipt of this report. All corrective actions must be completed satisfactorily within six months of the date of receipt.

Example of How to Submit your CAP Response with the Proposed/Completed Corrective Actions

Finding # XX

<Description of Finding cited by LELAP>

Regulation or Standard that establishes the Quality System Requirement:
LAC: <For LELAP use only>
NELAC: <For LELAP use only>

Description of Laboratory Corrective Action: *Provide a detailed narrative discussion of your proposed corrective action here.*

Laboratory Proposed Completion Date: *Insert date here*
Responsible Party: *Insert name of responsible party here*

LELAP Response to Proposed Corrective Action: <For LELAP use only>

Additional LELAP Comments (if necessary): <For LELAP use only>

Finding # 1

<Finding>

Regulation or Standard that establishes the Quality System Requirement:
LAC: § 5301.C.7
NELAC: § 5.4.3.1

Description of Laboratory Corrective Action:

Laboratory Proposed Completion Date:
Responsible Party:

LELAP Response to Proposed Corrective Action:

Additional LELAP Comments (if necessary):

*<**Instructions to Assessor on List of Findings**: An electronic copy of the List of Findings with the instructions from the previous page is to be included on CD **as a separate document**, in MS Word format. The electronic copy of the List of Findings is to be used by the laboratory for their corrective action response, and will be the same as the List of Findings that is included as part of the assessment report. **The List of Findings for the CAP response will be the ONLY document using MS Word format to be provided on the CD.** All other electronic documents on the CD will be in PDF or other non-editable electronic format. An electronic copy of the final assessment report will also be provide, but in PDF format so it can not be edited. The PDF copy of the assessment report will include a scanned copy of the signed cover page.*

Multi-part findings must be done using standard outline numbering, as per the example below.

Finding #1
A. Secondary Level
B. Secondary Level
i. Tertiary Level
ii. Tertiary Level
Finding #2
A. Secondary Level
…etc…

Appendix B
EVALUATION OF INSPECTORS

To improve the quality and receptiveness of our service to you and to maintain the quality of the laboratory inspection process, we request you complete the following evaluation. Since your comments are very important, please use the reverse side of this form to discuss issues not addressed in the items below. Please return this evaluation to:

Office of Environmental Assessment
Louisiana Environmental Laboratory Accreditation Program
P.O. Box 4314
Baton Rouge, LA 70821-4314
Attn: Paul Bergeron

INSPECTOR'S NAME:_____

TIME INSPECTOR ARRIVED:_____ LEFT_____

ITEM	STRONGLY DISAGREE	DISAGREE	NEUTRAL	AGREE	STRONGLY AGREE
The inspector contacted you in advance to arrange for you assessment and answered your questions concerning needed documentation, time for preparation, and other concerns.					
The inspector arrived on time at the agreed upon time and place.					
The goals and objectives of the surveys were clearly delineated in the initial meeting.					
The inspector's appearance and dress were professional and businesslike.					
The inspector's questions and comments were pertinent to laboratory operations and inspection.					

The inspector interacted with your staff in a courteous, helpful, and professional manner.					
The assessment findings were reflective of your laboratory's normal operations.					
The assessment results were summarized in an exit interview following the assessment.					
Correcting the findings noted in the exit report will improve your laboratory's operations and data quality.					
The inspector's comments have been/will be helpful to your laboratory staff and laboratory operations.					
The laboratory certification program is beneficial for your laboratory's analytical performance and professional marketability.					

OPTIONAL – LABORATORY NAME:_____